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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,084	10/28/2003	Mark B. Chandler	215063.02504	1154

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/694,084

Applicant(s)

CHANDLER ET AL.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/18/03
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____

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1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: It does not state that the person making the oath or declaration believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought.

2. Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 12 of claim 1, the phrase "the mixture" lacks antecedent basis. See this same problem on line 13 of claim 2.

In part e) of claim 2, the phrase "combining the reacted samples" should be changed to – combining the reacted aliquots—since there is only one sample recited in claim 2 with multiple aliquots. On the last line of claim 2, the phrase "of analyte in each sample" should be changed to –of each analyte in the sample—since claim 2 recites the determination of multiple analytes in a single sample.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1 and 2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14 and 16 of U.S. Patent No. 6,649,414. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a method of determining the concentration of an analyte in multiple samples or the concentration of multiple analytes in a single sample by providing a population of microparticles, wherein the microparticles include distinct subpopulations which are each uniquely labeled so as to provide a specific subpopulation characteristic detectable by an instrument, and wherein each subpopulation also has attached thereto either the same reagent for reacting with the same analyte or different reagents for reaction with different analytes, contacting a sample or samples with the different subpopulations of microparticles, allowing the analytes and reagents on the microparticles to react, identifying the subpopulations of microparticles in an instrument by measuring their unique characteristics, and measuring and calculating the results of the reagent/analyte reactions to determine the concentration of the analytes in the sample(s). The only difference between the sets of claims is that the instant claims recite the microparticles in each subpopulation being labeled with two characteristic

labels instead of one. It would have been obvious to one of ordinary skill in the art to label the microparticles of each subpopulation used in the method of claims 14 and 16 of US patent no. 6,649,414 with two labels instead of one so as to increase the permutation number of unique combinations of labels that can be used to distinguish the subpopulations, and to further distinguish the subpopulations from one another that may appear very similar with only one label.

6. Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No. 6,268,222. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a method of determining the concentration of multiple analytes in a single sample by providing a population of microparticles, wherein the microparticles include distinct subpopulations which are each uniquely labeled so as to provide a specific subpopulation characteristic detectable by an instrument, and wherein each subpopulation also has attached thereto different reagents for reaction with different analytes, contacting the sample with the different subpopulations of microparticles, allowing the analytes and reagents on the microparticles to react, identifying the subpopulations of microparticles in an instrument by measuring their unique characteristics, and measuring and calculating the results of the reagent/analyte reactions to determine the concentration of the analytes in the sample. The only difference between the sets of claims is that the instant claims recite the microparticles in each subpopulation being labeled with two characteristic labels instead of one. It would have been obvious to one of ordinary skill in the art to label the microparticles of each subpopulation used in the method of claim 15 of US patent no. 6,268,222 with two labels instead of one so as to

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increase the permutation number of unique combinations of labels that can be used to distinguish the subpopulations, and to further distinguish the subpopulations from one another that may appear very similar with only one label.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Chandler et al (WO 97/14028).

Chandler et al teach of a multiplexed method for the analysis of a plurality of analytes in a single clinical sample. The method comprises the first step of obtaining microparticles in the form of a beadset, wherein the microparticles are broken down into unique subsets or subpopulations. Each subset of microparticles is uniquely labeled with at least two labels that provide at least two characteristic classification parameters in an instrument such as a flow cytometer. The unique classification parameters include forward light scatter, side light scatter and fluorescent emission at different wavelengths. The microparticles in each subset contain the same unique labels and characteristic parameters. Each of the subsets are sufficiently different from any other subset in at least two of the classification parameters so that the profile of classification parameters within each subset is detectable by flow cytometry. Each of the microparticles in each subset is also coupled to a different reagent that will specifically react with a selected analyte of interest. Aliquots of a sample to be tested are mixed with each of the subpopulations of microparticles under conditions that allow reactions between the analytes of

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interest in the aliquots and the reactants on the different subpopulations of microparticles. The reacted aliquots are combined and analyzed by a flow cytometry instrument to determine their classification parameters and a parameter unique to the reaction between the analytes and the reagents. Each subset of microparticles is identified using the measured characteristic parameters. The presence or absence of a particular analyte in the sample is determined by measuring the results of the reactions between the reagents on the microparticles and the analytes. See pages 7-10 of Chandler et al.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler et al (WO 97/14028). For a teaching of Chandler et al, see previous paragraphs in this Office action.

Chandler et al fail to teach of using the multiplexed method for determining the concentration of an analyte in a multiplicity of different samples from different origins.

However, it would have been obvious to one of ordinary skill in the art at the time of the instant

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invention to do so since the method taught by Chandler et al is applicable for the detection of analytes in pooled samples and for the simultaneous analysis of multiple samples in an automated fashion, thus allowing many different samples to be analyzed at the same time for the same analyte by attaching only a single reagent to all of the subpopulations of microparticles.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Chandler et al (US Patent no. 6,632,526) and Kauvar et al who teach of microparticles containing different labels so as to produce different characteristic parameters.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

September 7, 2004

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